

### **REMARKS**

Claims 89, 90, 93, 97, 104 and 109 are pending following entry of the amendment above. Claims 84, 91, 92, 95, 96, 98-103 and 114 have been canceled without prejudice, and claims 89, 93, 97 and 109 have been amended to recite dependency from claim 104. Claim 104 has also been amended to delete the claim language "in an amount effective to provide a protective immune response" to provide greater clarity to the claim language. Applicants note for the record that this is not a narrowing amendment. These amendments have been made to put this application in condition for allowance and raise no new issues, and Applicants respectfully request entry thereof.

Applicants note with appreciation that the finality of the previous Office Action has been withdrawn. The remaining rejection under 35 U.S.C. §103 is addressed below.

#### **Interview Summary.**

Applicants wish to express their appreciation for the Examiner's time and courtesy during the telephonic interview of March 5, 2004 with Applicants' representative. During the telephonic interview, the Dubensky reference and Caley Declaration were discussed.

#### **Rejection under § 103.**

The previous rejection has been modified; claims 84, 90-93 and 95-114 are currently rejected as unpatentable for obviousness over Dubensky in view of Johnston 1 and 2. This rejection is addressed with respect to pending claims 89, 90, 93, 97, 104 and 109. The Final Action acknowledges that "because the Applicant has demonstrated unexpected results in the model described in the Olmsted supplemental reference, the rejection is withdrawn to the extent of the replicon vector described therein (i.e., the VEE replicon encoding the neu (Her2) antigen)" (Final Action, page 7, lines 8-10). The Final Action continues by stating that "[h]owever, as the Applicant has not

established that such results would also be found using any antigen, the rejection is maintained for the reasons above and for the reasons of record" (Final Action, page 7, lines 11-12).

Applicants disagree with the outstanding rejection and further respectfully submit that the rejection is insufficient to establish a *prima facie* case of obviousness with respect to the claimed invention for the reasons discussed at length in Applicants' previous responses. Nonetheless, to bring the lengthy prosecution of this application to a conclusion, the claims have been amended to recite Venezuelan Equine Encephalitis virus (VEE) replicons and the Her2 (neu) antigen without prejudice to the filing of a continuation application to continue prosecution of the previous claims. These claim amendments should not be construed as acquiescence or agreement with the outstanding rejection, but have been presented to expedite the allowance of this application. As the claims are all drawn to subject matter that was indicated as allowable in the Final Action, it is requested that the § 103 rejection over Dubensky in view of Johnston 1 and 2 be withdrawn.

As one final matter, Applicants wish to briefly address the comments at page 4 (para. 2) of the Final Action. Without introducing any further confusion into the prosecution of this application, Applicants wish to note that the cited statement in the Caley Declaration regarding replicon particles (*i.e.*, "replicon particles are capable of one round of infection; they cannot spread (*i.e.*, infect) other cells.") does not contradict any of Applicants' previous arguments, in particular, Applicants' previous statements regarding attenuating mutations. The previous assertions referenced by the Final Action address attenuating mutations and state that the modifications to the alphavirus genome described by Dubensky are not attenuating mutations. There is no contradiction between this assertion and the cited statement in the Caley Declaration.

The concerns of the Examiner having been addressed in full, Applicants respectfully request withdrawal of the outstanding rejection and the

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issuance of a Notice of Allowance forthwith. The Examiner is encouraged to address any questions regarding the foregoing to the undersigned attorney, who may be reached at (919) 854-1400. The Commissioner is hereby authorized to charge Deposit Account No. 50-0220 for any additional extension and/or fee required or credit for any excess fee paid.

Respectfully submitted,



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**CERTIFICATE OF EXPRESS MAILING**

"Express Mail" mailing label number: EV472536528US  
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I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.



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